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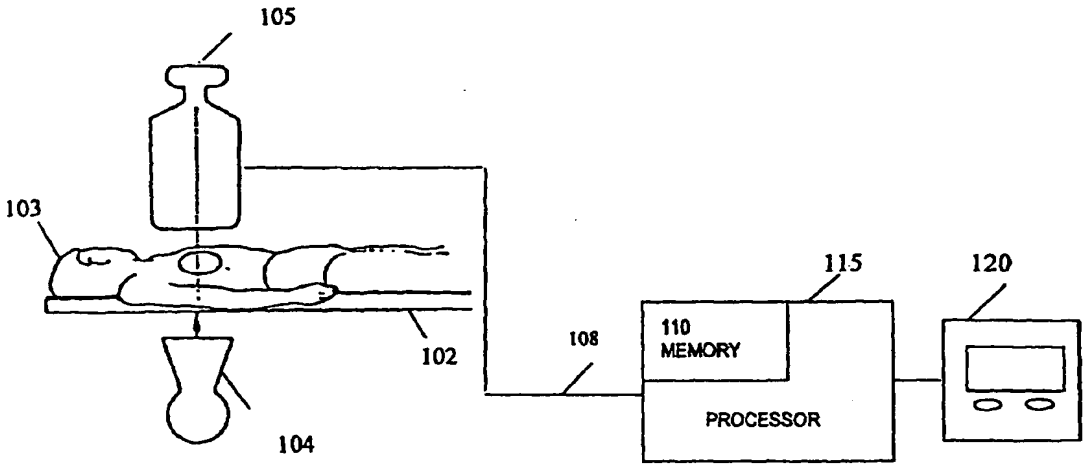
(54) Title: METHOD AND SYSTEM FOR POSITIONING A DEVICE IN A TUBULAR ORGAN



(57) Abstract: A system and method for positioning a device at a desired location in a tubular organ such as an artery. A three-dimensional reconstruction of the organ is obtained, and the desired location is marked in the reconstruction. The device is inserted into the organ and an image is obtained of the device and organ. The reconstruction with the marked location is projected onto a plane from the perspective of the image and the projection and image are superimposed. If the device is not at the desired location, the device is repositioned in the organ and an additional image of the device is obtained. The reconstruction is then projected onto a plane from the perspective of the additional image and the additional image and the projection are superimposed. This process is repeated, as required, until the device is in the desired location.

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METHOD AND SYSTEM FOR POSITIONING A DEVICE IN A TUBULAR ORGAN

FIELD OF THE INVENTION

The present invention relates to methods of positioning a device in a tubular organ of the body.

BACKGROUND OF THE INVENTION

Interventional radiology procedures are becoming increasingly important in the treatment of physiological abnormalities such as lumen stenosis or aneurysm. For example, in order to treat a stenotic coronary artery, it is often required to inflate a balloon, apply an atherectomy or thrombectomy device and place a stent (prosthesis) at a diseased artery site. The intravascular device (balloon, stent, atherectomy or thrombectomy device, for example) is usually mounted onto a guide wire and brought to the vessel to be treated using the guide wire and a catheter. When the catheter tip has reached the arterial region to be treated, the guide wire is extended from the catheter tip and is used to position the device inside the artery. Once the device is positioned within the artery and deployed, repositioning of the device is either impossible or may significantly increase the risk of injury to the artery and can result in total blockage to the treated artery.

Accurate positioning of the intravascular device at a specific site within an artery is essential for successful treatment. Improper positioning of a stent at the diseased site within the artery, or use of a longer stent than is actually required in order to compensate for inaccurate positioning, may significantly increase the chance for subsequent renarrowing of the artery. Moreover, in atherectomy procedures, inaccurate positioning and deployment of the device in the artery may cause a fatal thrombosis. Therefore, accurate determination of the location of an

intravascular device in an artery is vital during any interventional therapeutic procedure.

The location of a catheter tip or intravascular device with reference to surrounding arterial anatomy is monitored by X-ray fluoroscopy. An angiographer releases a contrast material, such as iodine solution, from the catheter tip. The contrast material is carried from the catheter tip by the blood flow, and an X-ray image of the arterial anatomy in the vicinity of the catheter tip is obtained. Based upon the obtained X-ray image, the catheter is advanced until the desired arterial anatomy is reached. Then, the guide wire is extended from the catheter tip and brought to the diseased artery using fluoroscopy and short injections of contrast material. Usually, in order to treat the artery, the tip of the guide wire should pass through the diseased region to the distal end of the diseased region. Subsequently, an intravascular device is extended over the guide wire and brought to the diseased arterial region. Monitoring the location of the device inside the artery is performed by following the movement of two radio-opaque markers slidable along the guide wire that flank the device. The markers indicate the position of the device in reference to the guide wire in conjunction with short injections of contrast material. Typically, prior art methods require that the device be introduced stepwise into the organ and at each step the device and organ imaged so as to show the instantaneous position of the device relative to the organ. This is repeated as required until the device is positioned at the desired location. Such an approach requires that a contrast material be released into the organ in order for the organ to be imaged together with the device. Since many images may be required, the total amount of contrast material released into the blood may be quite large and harmful to the patient. Moreover, determining the location of the device in an artery in relation to the region to be treated is often inaccurate by this method. The main reason for this may be attributed to the fact that assessment of the morphology and length of disease in the artery is strongly dependent on the perspective from which the artery is viewed.

It would therefore be desirable to provide a method and system where re-imaging of the organ for each incremental advance of the device in the organ is avoided.

SUMMARY OF THE INVENTION

The present invention provides a method and system for positioning a device in a tubular organ such as an artery, a blood vessel, or a urethra. The device encompasses, for example, intravascular devices, such as, catheters, balloons, stents, atherectomy and thrombectomy devices.

In accordance with the invention, positioning of the device in a tubular organ, such as an artery is performed utilizing a three-dimensional computer reconstruction of the organ. In the case of an artery, a three-dimensional reconstruction of the artery may be displayed on a monitor screen from any selected perspective. This allows a diseased artery, for example, to be viewed in the reconstruction from a perspective that is optimal for assessing the morphology and the length of disease in the artery. This in turn permits accurate determination of a location where an intravascular device should be deployed. A three-dimensional reconstruction of an artery may be obtained for example, as disclosed in Applicant's co-pending United States Patent Application Serial Number 09/662,325 entitled "*System and Method for Three-Dimensional Reconstruction of an Artery*" filed on September 14, 2000. The reconstruction is displayed on a monitor screen, and the location where the device is to be deployed is determined and marked in the reconstruction taking into consideration the abnormality characteristics, the nominal dimensions of the device and its dimensions after deployment.

The device is mounted on a guide wire and is brought to the desired arterial region by a catheter, as is known in the art. Then, the guide wire is extended from the catheter tip and is used to navigate inside the arterial anatomy until the target artery has been reached.

In accordance with one embodiment of the invention, the device is inserted into the artery along the guide wire and an X-ray image of the artery, the guide wire and the device is obtained. The location of the device in the artery is determined by following the movement of two radio-opaque markers along the guide wire as the device moves along the guide wire. Then, a two-dimensional projection of the reconstruction, including the region marked for deployment, is obtained from the same perspective as the image, and superimposed onto the image. The superimposition thus shows simultaneously the device and the region of the artery marked in the reconstruction for deployment of the device. The device is advanced in the artery based upon a comparison of the present location of the device in the artery and the location of the marked region. A new image is then obtained of the device, and a superimposition of the reconstruction with the marked arterial region is obtained from the same perspective of the new image. Based upon a comparison of the new location of the device in the artery and the location of the marked region, the device is advanced towards the desired region. This process is repeated until the device appears in an image in the region of the artery marked in the reconstruction for deployment.

In accordance with another embodiment of the invention, two or more images of the artery are obtained and a three-dimensional computer reconstruction of the artery is generated from the images. The location at which the device is to be deployed is then determined and marked in the reconstruction taking into consideration the abnormality characteristics, the nominal dimensions of the device and its dimensions after deployment. Contrast material is released from the catheter tip and an image of the artery to be treated and the device carried over a guide wire is obtained, preferably from the perspective of one of the images used to generate the computer reconstruction. The location of the device in the artery is determined by following the movement of two radio-opaque markers along the guide wire as the device moves along the guide wire. Then, the position of the device in the artery is marked in the reconstruction and compared to the desired location as indicated in the reconstruction. If the device is at the desired location, then the process

terminates. Otherwise, the device is advanced in the artery towards the desired location and a new fluoroscopic image of the device and the guide wire is then obtained from the same perspective without releasing contrast material from the catheter tip. The new location of the device in the artery is then determined from the position of the two radio-opaque markers and is then updated in the reconstruction. This process is repeated until the device is positioned in the desired location.

Thus, in its first aspect the invention provides a method for positioning a device, at a desired location in a tubular organ comprising:

(a) generating a three-dimensional reconstruction of the organ;

(b) marking the desired location in the reconstruction;

(c) inserting the device into the organ;

(d) obtaining an image of the device and the organ, the image having been obtained from a perspective; and

(e) using the three-dimensional reconstruction of the organ in combination with the image of the device to position the device at said desired location in the organ.

The invention further provides a system for positioning a device at a desired location in a tubular organ, comprising:

an imaging system for imaging the organ,

a processor configured to:

i) generate a three-dimensional reconstruction of the organ;

ii) project the three-dimensional reconstruction onto a plane from a perspective of an image and superimpose the projection onto the image;

a display displaying the superimposition.

The invention additionally provides a program storage device readable by machine, tangibly embodying a program of instructions executable by the machine to perform method steps for positioning a device at a desired location in a tubular organ, said method steps comprising:

(a) generating a three-dimensional reconstruction of the organ;

(b) projecting the three-dimensional reconstruction onto a plane from a perspective of an image; and

(c) superimposing the projection onto the image.

The invention further provides computer program product comprising a computer useable medium having computer readable program code embodied therein for positioning a device at a desired location in a tubular organ, the computer program product comprising:

computer readable program code for causing the computer to generate a three-dimensional reconstruction of the organ;

computer readable program code for causing the computer to project the three-dimensional reconstruction onto a plane from a perspective of an image; and

computer readable program code for causing the computer to superimpose the projection onto the image.

The invention additionally provides a method for positioning a device, at a desired location in a tubular organ, comprising:

(a) obtaining a first image of the organ, the image having been obtained from a perspective, and generating a three-dimensional reconstruction of the organ based upon the image;

(b) marking the desired location in the reconstruction;

(c) inserting the device into the organ;

(d) obtaining a second image of the device and the organ, the second image being obtained from the same perspective as the first image;

(e) marking in the reconstruction the location of the device in the organ;

(f) if the device is not located at the desired location, then:

i) repositioning the device in the organ;

ii) obtaining an image of the device;

iii) repeating (e) and (f) as required until the device is located at the desired location.

The invention further provides a system for positioning a device at a desired location in a tubular organ, comprising:

an imaging system for imaging the organ;

a processor configured to:

i) receive data indicative of the desired location in the organ;

ii) receive data indicative of the location of the device in the organ; and

iii) mark in the reconstruction the desired location and the location of the device in the organ; and

a display for displaying the reconstruction.

The invention additionally provides program storage device readable by machine, tangibly embodying a program of instructions executable by the machine to perform method steps for positioning a device, at a desired location in a tubular organ, said method steps comprising:

(a) generating a three-dimensional reconstruction of the organ based upon a first image of the organ obtained from a perspective;

(b) receiving data indicative of the location of the desired region in the reconstruction;

(c) determining the location of the device in the organ from a second image obtained from the same perspective as the first image and

marking in the reconstruction the location of the device in the organ.

The invention also provides a computer program product comprising a computer useable medium having computer readable program code embodied therein for positioning a device, at a desired location in a tubular organ, the computer program product comprising:

computer readable program code for causing the computer to generate a three-dimensional reconstruction of the organ based upon a first image of the organ obtained from a perspective;

computer readable program code for causing the computer to receive data indicative of the location of the desired region in the reconstruction;

computer readable program code for causing the computer to determine the location of the device in the organ from a second image obtained from the same perspective as the first image and

computer readable program code for causing the computer to mark in the reconstruction the location of the device in the organ.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 shows a system for positioning a device in an artery according to one embodiment of the invention;

Fig. 2 shows a device being navigated through an arterial system;

Fig. 3 shows a flow chart diagram for positioning a device in an artery in accordance with one embodiment of the invention; and

Fig. 4 shows a flow chart diagram for positioning a device in an artery in accordance with another embodiment of the invention.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

Referring first to Fig. 1, shown is a system for positioning a catheter or intravasicular device at a desired location within an artery in accordance with one embodiment of the invention. The system comprises a table **102** upon which a patient **103** lies. An X-ray source **104** is located under the table **102** for projecting X-rays through the patient **103** to an X-rays camera **105** located above the table **102**, diametrically opposite the X-rays source **104**. The X-ray camera **105** generates video signals **108** representing one or more X-ray images of the patient **103**. The video signals **108** are stored in a memory **110** of a processor

115. Images captured by the X-ray camera **105** may be viewed on a monitor **120** either in real-time or after being retrieved from the memory **110**.

Fig. 2 shows a catheter **200** the tip **205** of which has been positioned at an aperture **212** of an artery **210** that is part of an arterial tree **215** of the patient **103**. The catheter **200** may be used to deliver an intravascular device **218** mounted on a guide wire **216** to a desired location **219** within the artery **210**. The catheter **200** is connected to a reservoir **220** containing a radio-opaque liquid **221** such as an iodine solution that is conducted from the reservoir **220** to the catheter tip **205** and released from the catheter tip **205** as required by depressing a piston **222**. When contrast material **221** is released from the catheter tip **205**, an image is obtained of the arterial tree in the vicinity **235** of the catheter tip **205** by the X-ray camera **105**. Based upon the obtained image, the catheter tip is brought to the arterial system **215**, which contains the artery to be treated **210**. Then, the guide wire **216** is extended from the catheter tip **205** and brought to the diseased region within an artery **219** using fluoroscopy and short injections of contrast material. After positioning of the guide wire **216** within the artery **210**, the device **218** is inserted into the artery **210** towards the desired region to be treated **219** along the guide wire **216**.

Fig. 3 is a flow chart showing the principal steps for navigating the device **218** to the desired location **219** in accordance with one embodiment of the invention. In step **300**, two or more images of the artery are obtained. Then, a three-dimensional computer reconstruction of the artery is generated from the images (step **305**). Subsequently, taking into consideration the abnormality characteristics (for example, stenosis), the location where the device **218** is to be deployed is determined and marked in the reconstruction, and the nominal dimensions and its dimensions after deployment of the appropriate device are determined (step **310**). In step **320**, the contrast material **221** is released from the tip **205** of the catheter **200** and an image is obtained showing the position of the device **218** along the guide wire **216** as indicated by two radio-opaque markers flanking the device **218** on the guide wire, and the anatomy of the artery to be

treated **208**. In step **330**, the reconstruction of the artery with the marked region of interest is projected onto a plane from the same perspective as the image, and superimposed onto the image. The superimposition thus shows simultaneously the device **218** and the region **210** of the artery marked in the reconstruction for deployment of the device. Then, the present position of the device **218** is compared to the desired location **219** as indicated in the superimposition (step **340**). If the device **218** is at the desired location, then the process terminates (step **350**). If no, the device **218** is advanced in the artery towards the desired location (step **360**). Then, a new image of the device **218** is obtained (step **370**) and the process returns to step **340**.

Fig. 4 is a flow chart showing the principal steps for navigating the device **218** to a desired location within the artery **219** in accordance with another embodiment of the invention. In step **400**, two or more images of the artery **210** are obtained. Then, a three-dimensional computer reconstruction of the artery is generated from the images (step **405**). Then, the location at which the device is to be deployed is determined and marked in the reconstruction based upon the abnormality characteristics, the nominal dimensions of the device and its dimensions after deployment (step **410**). In step **420**, the contrast material **221** is released from the tip **205** of the catheter **200** and an image of the artery to be treated **208** and the device **218** carried over a guide wire **216** is obtained from the perspective of one of the images used to generate the computer reconstruction. In step **430**, the position of the device in the artery is determined from the position of two radio-opaque markers flanking the device on the guide wire, and marked in the reconstruction. Then, the position of the device **218** in the reconstruction is compared to the desired location **219** as indicated in the reconstruction (step **440**). If the device **218** is at the desired location, then the process terminates (step **450**). If not, the device **218** is advanced in the artery towards the desired location (step **460**). A new fluoroscopic image of the device **218** and the guide wire **216** is then obtained from the same perspective without releasing contrast material from the catheter tip (step **470**). The new location of the device in the artery is then

determined based upon following the two radio-opaque markers which represent its position along the guide wire and is then updated in the reconstruction and the process returns to step **440**.

It will also be understood that the system according to the invention may be a suitably programmed computer. Likewise, the invention contemplates a computer program being readable by a computer for executing the method of the invention. The invention further contemplates a machine-readable memory tangibly embodying a program of instructions executable by the machine for executing the method of the invention.

CLAIMS:

1. A method for positioning a device, at a desired location in a tubular organ comprising:

(a) generating a three-dimensional reconstruction of the organ;

(b) marking the desired location in the reconstruction;

(c) inserting the device into the organ;

(d) obtaining an image of the device and the organ, the image having been obtained from a perspective; and

(e) using the three-dimensional reconstruction of the organ in combination with the image of the device to position the device at said desired location in the organ.

2. The method according to Claim 1, wherein step **(e)** includes:

i) projecting the reconstruction with the marked location in the organ onto a plane from the perspective of the image and superimposing the projection onto the image;

ii) if the device is not located at the desired location, then:

(1) repositioning the device in the organ;

(2) obtaining an additional image of the device; and

(3) projecting the reconstruction with the marked location in the organ onto a plane from the perspective of the additional image and superimposing the projection onto the additional image;

iii) repeating step **ii)** as required until the device is located at the desired location.

3. The method according to Claim 1 or 2, wherein step **(b)** includes determining the desired position of the device from the three-dimensional reconstruction of the organ.

4. The method of any one of Claims 1 to 3, wherein the tubular organ is an artery.

5. A system for positioning a device at a desired location in a tubular organ, comprising:

an imaging system for imaging the organ,

a processor configured to:

i) generate a three-dimensional reconstruction of the organ;

ii) project the three-dimensional reconstruction onto a plane from a perspective of an image and superimpose the projection onto the image;

a display displaying the superimposition.

6. The system of Claim 5, wherein the tubular organ is an artery.

7. A program storage device readable by machine, tangibly embodying a program of instructions executable by the machine to perform method steps for positioning a device at a desired location in a tubular organ, said method steps comprising:

(a) generating a three-dimensional reconstruction of the organ;

(b) projecting the three-dimensional reconstruction onto a plane from a perspective of an image; and

(c) superimposing the projection onto the image.

8. The program storage device of Claim 7, wherein the tubular organ is an artery.

9. A computer program product comprising a computer useable medium having computer readable program code embodied therein for positioning a device at a desired location in a tubular organ, the computer program product comprising:

computer readable program code for causing the computer to generate a three-dimensional reconstruction of the organ;

computer readable program code for causing the computer to project the three-dimensional reconstruction onto a plane from a perspective of an image; and

computer readable program code for causing the computer to superimpose the projection onto the image.

10. The computer program product of Claim 0, wherein the tubular organ is an artery.

11. A method for positioning a device, at a desired location in a tubular organ, comprising:

(a) obtaining a first image of the organ, the image having been obtained from a perspective, and generating a three-dimensional reconstruction of the organ based upon the image;

(b) marking the desired location in the reconstruction;

(c) inserting the device into the organ;

(d) obtaining a second image of the device and the organ, the second image being obtained from the same perspective as the first image;

(e) marking in the reconstruction the location of the device in the organ;

(f) if the device is not located at the desired location, then:

i) repositioning the device in the organ;

ii) obtaining an image of the device;

iii) repeating **(e)** and **(f)** as required until the device is located at the desired location.

12. The method of Claim 11, wherein the tubular organ is an artery.

13. A system for positioning a device at a desired location in a tubular organ, comprising:

an imaging system for imaging the organ;

a processor configured to:

a) receive data indicative of the desired location in the organ;

b) receive data indicative of the location of the device in the organ; and

c) mark in the reconstruction the desired location and the location of the device in the organ; and

a display for displaying the reconstruction.

14. The system of Claim 13, wherein the tubular organ is an artery.

15. A program storage device readable by machine, tangibly embodying a program of instructions executable by the machine to perform method steps for

positioning a device, at a desired location in a tubular organ, said method steps comprising:

(a) generating a three-dimensional reconstruction of the organ based upon a first image of the organ obtained from a perspective;

(b) receiving data indicative of the location of the desired region in the reconstruction;

(c) determining the location of the device in the organ from a second image obtained from the same perspective as the first image and

(d) marking in the reconstruction the location of the device in the organ.

16. The program storage device of Claim 15, wherein the tubular organ is an artery.

17. A computer program product comprising a computer useable medium having computer readable program code embodied therein for positioning a device, at a desired location in a tubular organ, the computer program product comprising:

computer readable program code for causing the computer to generate a three-dimensional reconstruction of the organ based upon a first image of the organ obtained from a perspective;

computer readable program code for causing the computer to receive data indicative of the location of the desired region in the reconstruction;

computer readable program code for causing the computer to determine the location of the device in the organ from a second image obtained from the same perspective as the first image and

computer readable program code for causing the computer to mark in the reconstruction the location of the device in the organ.

18. The computer program product of Claim 17, wherein the tubular organ is an artery.

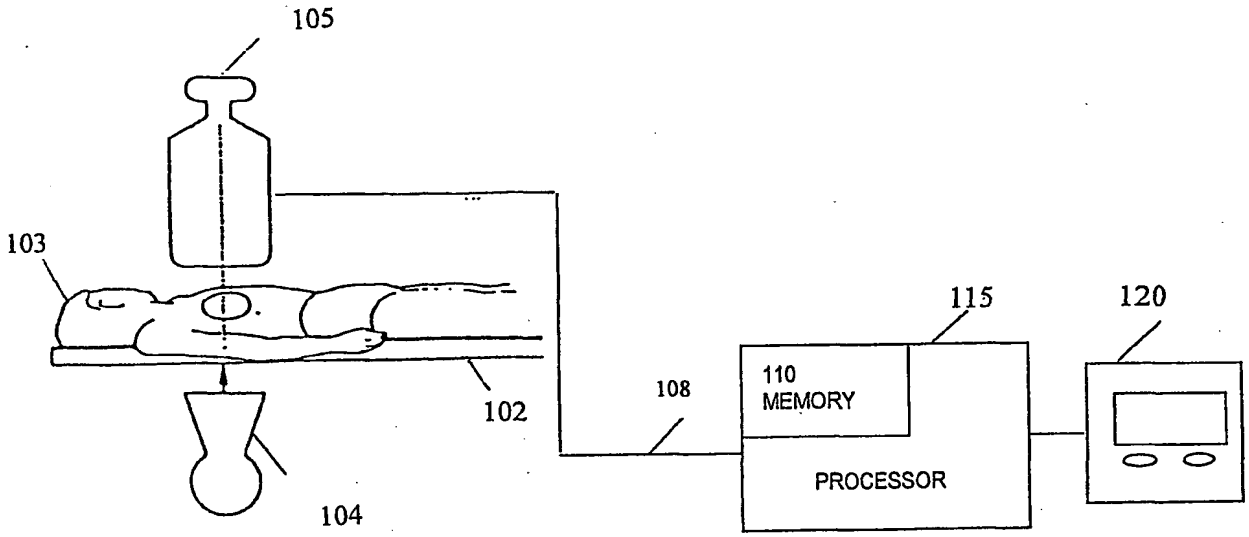

FIG. 1

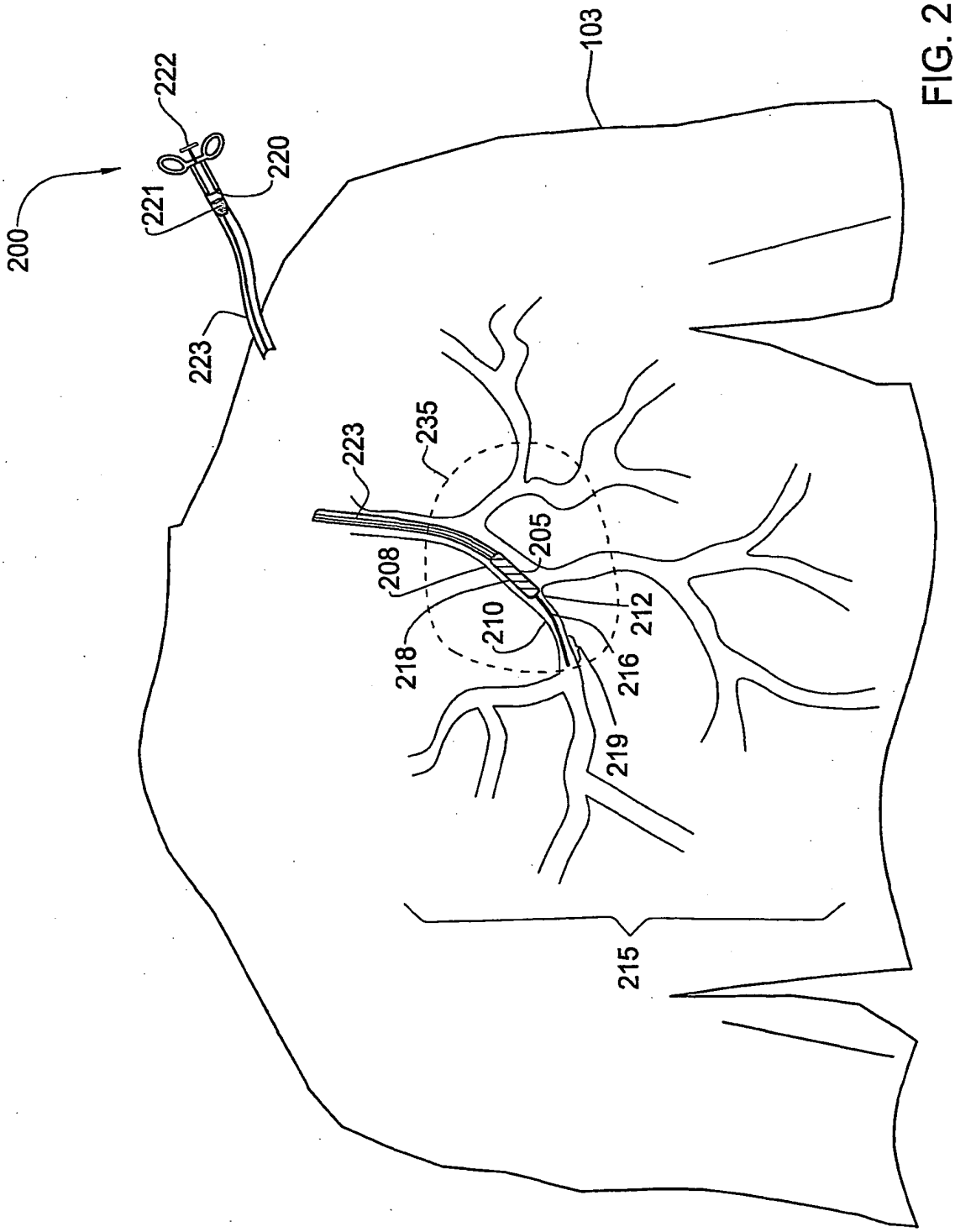

FIG. 2

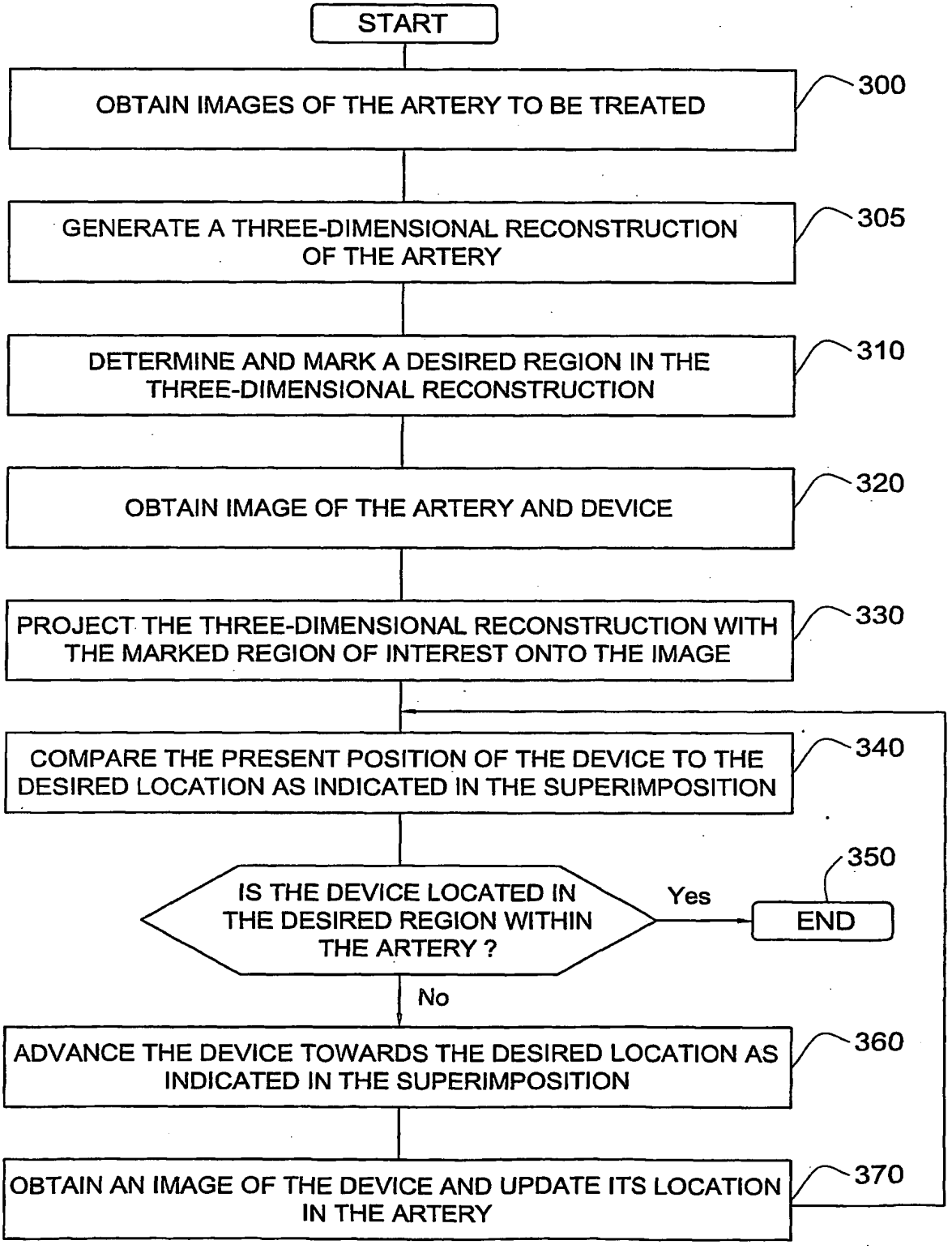
START
OBTAIN IMAGES OF THE ARTERY TO BE TREATED
300
GENERATE A THREE-DIMENSIONAL RECONSTRUCTION OF THE ARTERY
305
DETERMINE AND MARK A DESIRED REGION IN THE THREE-DIMENSIONAL RECONSTRUCTION
310
OBTAIN IMAGE OF THE ARTERY AND DEVICE
320
PROJECT THE THREE-DIMENSIONAL RECONSTRUCTION WITH THE MARKED REGION OF INTEREST ONTO THE IMAGE
330
COMPARE THE PRESENT POSITION OF THE DEVICE TO THE DESIRED LOCATION AS INDICATED IN THE SUPERIMPOSITION
340
IS THE DEVICE LOCATED IN THE DESIRED REGION WITHIN THE ARTERY ?
Yes
350
END
No
ADVANCE THE DEVICE TOWARDS THE DESIRED LOCATION AS INDICATED IN THE SUPERIMPOSITION
360
OBTAIN AN IMAGE OF THE DEVICE AND UPDATE ITS LOCATION IN THE ARTERY
370

FIG. 3

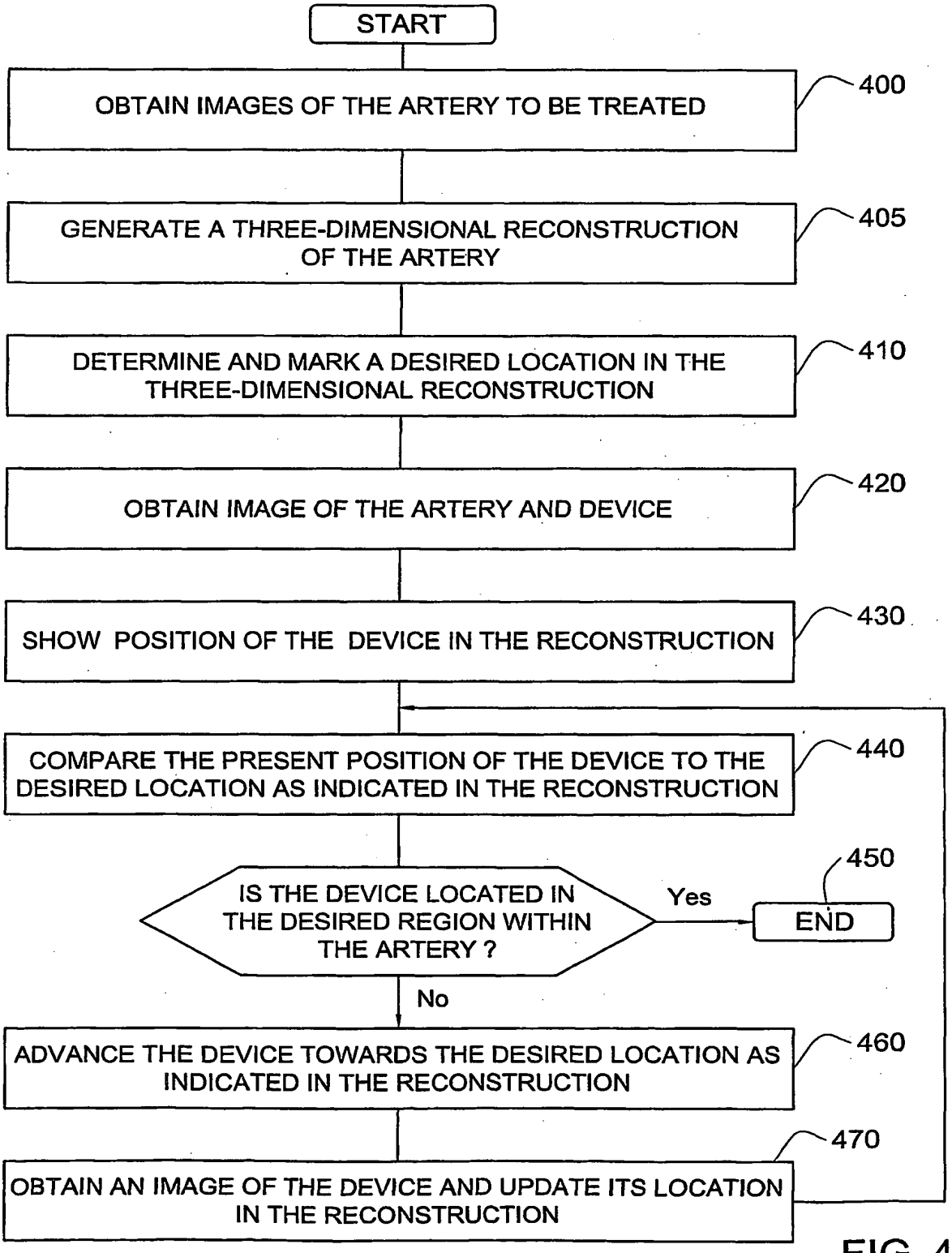
START
OBTAIN IMAGES OF THE ARTERY TO BE TREATED
400
GENERATE A THREE-DIMENSIONAL RECONSTRUCTION OF THE ARTERY
405
DETERMINE AND MARK A DESIRED LOCATION IN THE THREE-DIMENSIONAL RECONSTRUCTION
410
OBTAIN IMAGE OF THE ARTERY AND DEVICE
420
SHOW POSITION OF THE DEVICE IN THE RECONSTRUCTION
430
COMPARE THE PRESENT POSITION OF THE DEVICE TO THE DESIRED LOCATION AS INDICATED IN THE RECONSTRUCTION
440
IS THE DEVICE LOCATED IN THE DESIRED REGION WITHIN THE ARTERY ?
Yes
450
END
No
ADVANCE THE DEVICE TOWARDS THE DESIRED LOCATION AS INDICATED IN THE RECONSTRUCTION
460
OBTAIN AN IMAGE OF THE DEVICE AND UPDATE ITS LOCATION IN THE RECONSTRUCTION
470

FIG. 4

INTERNATIONAL SEARCH REPORT

PCT/IL 01/00955

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B6/00 A61B5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B G06T

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, BIOSIS, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 25881 A (UNSGAARD GEIRMUND ;OLSTAD BJOERN (NO); GROENNINGSAETER AAGE (NO)) 29 August 1996 (1996-08-29) page 25, line 3 - line 23 page 10, line 26 -page 16, line 20 page 23, line 6 -page 24, line 3; tables 1-4,7,10-17 ---	1-18
Y	WO 99 13432 A (UNIV IOWA RES FOUND) 18 March 1999 (1999-03-18) page 1, line 11 -page 5, line 5 page 10, line 18 -page 14, line 3; tables 2-4 --- -/--	1-18

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
15 April 2002	23/04/2002

Name and mailing address of the ISA	Authorized officer
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